

**REMARKS**

This paper is responsive to the Office Action mailed June 13, 2008. Applicants request entry of these remarks, and reconsideration and allowance of the application as so amended notwithstanding the finality of the Office Action.

**Status of the Claims**

Claims 1, 2, 4-10, 12-15, and 22-26 were examined.

Claims 1, 2, 4, 7, 13-15, 22, and 26 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Bond et al., U.S. Pat. No. 4,109,643 (hereinafter "Bond") in view of Falcone, U.S. Pat. No. 5,438,983 (hereinafter "Falcone").

Claims 5 and 6 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Bond in view of Falcone in further view of Kianl et al., U.S. Pat. No. 6,658,276 (hereinafter "Kianl").

Claims 8-10 and 23-25 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Bond in view of Falcone in further view of Masuda, U.S. Pat. No. 6,322,516 (hereinafter "Masuda").

Claim 12 stands rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Bond in view of Falcone in further view of Tham et al., U.S. Pat. No. 5,912,656 (hereinafter "Tham").

**The claims present patentable subject matter  
and should be allowed**

In the final Office Action, the Office appears to propose two distinct bases for maintaining the rejections.

In a first basis, the Office argues that Falcone teaches activating an alarm if the parameter values are above or below a predetermined threshold, citing Falcone col. 2 lines 15-20 and 47-60 and col. 5 lines 36-58. Office Action at page 3.

Actually, Falcone teaches a two-step alarm process. First, a parameter is determined to be outside of a safe zone limit. Falcone col. 2 lines 15-17. Then, the trend vector is calculated and compared with an alarm limit function and issues an alarm if the trend vector exceeds the alarm limit function. Falcone col. 2 lines 17-20. The remaining passages disclose the same approach.

Thus, if one hears Falcone's alarm, one does not learn about any relative deviations with respect to the reference value. Rather, one learns that a trend has been exceeded. A trend is not a relative deviation. A trend (as used in Falcone) is a derivative value, i.e.  $\frac{dV}{dt}$  (or perhaps a partial derivative  $\frac{\partial V}{\partial t}$ ). The claims of the present application have nothing to do with derivative or trend values. The present application relates to relative deviations, i.e.  $(V(x) - V_{ref})$  where  $V(x)$  is a current parameter value and  $V_{ref}$  is the reference parameter value.

The second basis for maintaining the rejections set forth in the Office Action is the trend line shown in Falcone Fig. 6. The Office argues that "[t]he reference value in this situation can be any point in the specified window for example the starting point of the waveform graph in the predetermined window of time or any point in time during that specific period." Office Action at page 3.

One *could* select the starting point or any other point in time on the waveform as a reference value, and then look at the difference between the current value shown on the graph and that reference value and attempt to "visually subtract" the ordinate values of these two points to determine the relative deviation. It would not be a very good approach, since the "visual subtraction" would be prone to error, but it could be done.

Such an operation might be suggested to one in *hindsight*, after reading the present application. However, nothing in *Bond* or in *Falcone* or in *their combination* suggests performing this operation.

Respectfully, the Office in asserting this second basis is using the present application as a blueprint to decide to perform operations not remotely suggested in the references. The suggestion to select a reference value and to perform such "visual subtraction" is not found in the references or in the state of the art at the time of invention, but rather in the Office Action prepared after reading the present application, and after reading Applicants' identification of deficiencies of the *Bond* and *Falcone* references. *Falcone* does not disclose or fairly suggest a reference value, much less determining a relative deviation respective to a reference value.

*Bond* teaches only displaying the current perfusion index value. *Falcone* goes beyond *Bond* in recognizing the advantage of looking at temporal evolution, but

Falcone teaches a materially different alternatively method, namely displaying a trendline and activating alarms based on the trend or derivative of the value. Far from suggesting the methods and devices recited in the present claims, which employ a relative deviation display, Falcone teaches away from these claims by advocating a wholly different approach, namely displaying the trendline or derivative, rather than looking at relative deviations.

**Claim 1** recites defining a first perfusion index as a reference value selected from perfusion index values determined during the photometric measuring process; determining subsequent perfusion indices as relative deviations with respect to the reference value; displaying the reference value on the display unit; and presenting said relative deviations as information concerning the variations of the perfusion on the display unit.

Falcone does not define a first perfusion index as a reference value selected from perfusion index values determined during the photometric measuring process. The Office Action derives this operation from Falcone's trend line – the Office (not Falcone) selects one of the points on the trend line as a reference value. Nothing in Falcone suggests doing so.

Falcone does not determine subsequent perfusion indices as relative deviations with respect to the reference value. The Office Action suggests performing this operation by proposing to visually subtract the current perfusion index value of the trendline from the reference value.

Falcone does not present said relative deviations as information concerning the variations of the perfusion on the display unit. Falcone presents the *absolute value* of the perfusion index measurements, along with the *trend or derivative* of these measurements. Nothing in Falcone suggests presenting relative deviations in any way whatsoever – Falcone cannot do so, since Falcone neither defines a reference value nor determines relative deviations with respect to the reference value.

**Claim 22** recites a display unit configured to display a first graphical element indicative of a reference perfusion index value derived from the provided perfusion data at a reference time, and a second graphical element indicative of a subsequent perfusion index value derived from the provided perfusion data at a subsequent time, wherein the display unit displays the first and second graphical elements together to

provide a visual indication of a relative deviation of the subsequent perfusion index value from the reference perfusion index value.

In rejecting claim 22, the Office cites Falcone's display of the trend arrow (providing magnitude and polarity of the trend or derivative) and Falcone's display of a waveform or current parameter. Office Action at pages 7-8. From this, the Office concludes:

Therefore it would have been obvious ... to have displayed a trend of the change in the values of the physiological parameters collected, similar to the teachings of Falcone, with the perfusion meter of Bond, in order to monitor the trend of change in the physiological parameter, so that the physician or health provider could look at the monitor and know, not just what the current parameter values are, but what the parameter values have been doing over a specified time (Col. 6 lines 22-28 of Falcone).

Office Action at page 8.

This argument for obviousness conflates the trend (derivative) of Falcone with the relative deviation of the present application. These are two wholly different concepts – different mathematical formulae, different quantitative values, different underlying physical significance.

It would also have been obvious to have replaced the display system of Bond with the one taught in Falcone in order to display different physiological parameters of the patient on the same screen [as] this would give the clinician more information regarding the health status of a patient.

Office Action at page 8.

Most claims of the present application are unrelated to display of different *types* of physical parameters (e.g., ECG, heart rate, perfusion index, etc.) together. The present application relates to display of the perfusion index, which may or may not be done in conjunction with display of other parameters. Dependent claim 12 does recite wherein the display is formed as a multidimensional type in conjunction with other physiological variables, which clarifies that the method of claim 1 may be performed

in that context. Dependent claim 26 also recites the display unit is further configured to display arterial O<sub>2</sub> saturation determined by the pulsoximeter. Hence claims 12 and 26 are related to multi-parameter display, but the remaining claims are more general, and accordingly the above argument of the Office is irrelevant to most claims.

On the other hand, to the extent that Falcone may be read as advocating the maximization of displayed *perfusion index* information content (e.g., display of a trend line together with trend vectors going back 15 minutes in time) Falcone again teaches away from claim 22. This claim is directed to a readily perceived graphical representation of the improvement (or lack thereof) of the current perfusion index reading for a patient as compared with a previous reference perfusion index value for that patient. This is an intuitive display that is *uncluttered* by complex trend arrows (which require understanding of Calculus to fully comprehend) or absolute perfusion index values, which are of limited clinical value unless placed into context for a particular patient, which is precisely what the claims of the present application do by displaying the *relative deviation* from a *reference value* specific to the patient.

For the reasons set forth above, it is submitted that claims 1, 2, 4-10, 12-15, and 22-26 distinguish patentably over the references of record and meet all statutory requirements. Reconsideration and allowance of claims 1, 2, 4-10, 12-15, and 22-26 is earnestly requested.

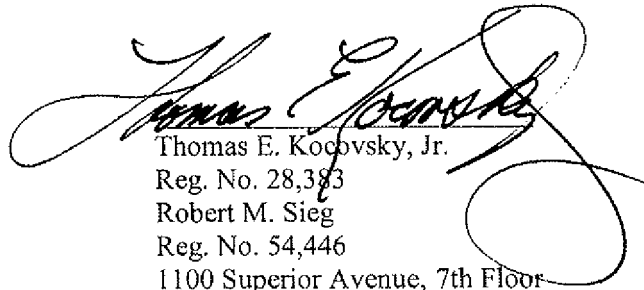
**CONCLUSION**

For the reasons set forth above, it is submitted that claims 1, 2, 4-10, 12-15, and 22-26 distinguish patentably over the references of record and meet all statutory requirements. An early allowance of all claims is requested.

In the event personal contact is deemed advantageous to the disposition of this case, the Examiner is requested to telephone the undersigned at (216) 861-5582.

Respectfully submitted,

FAY SHARPE LLP

A large, stylized handwritten signature in black ink, which appears to read "Thomas E. Kocovsky, Jr.", is written over the printed name and address.

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